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# PierianDx Customers Cite 'Creative Partnership' on Clinical Genomics as Key Selling Point

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NEW YORK (GenomeWeb) – Last week, PierianDx announced six new customers for its Clinical Genomicist Workspace (CGW), including Cedars-Sinai Medical Center, Dartmouth-Hitchcock Medical Center, Florida Hospital, Georgia Esoteric & Molecular Laboratory at Augusta University, NorthShore University HealthSystem, and the University of Arkansas for Medical Sciences.

That brings the customer count to more than 40 and is key to realizing what PierianDx considers to be equally important to CGW, its one-stop shop for clinical genomics: a network of leading pathologists, generating a proprietary knowledgebase of clinically actionable information.

"We saw the benefits of this network on day one," Niki Sidiropoulos, medical director at the University of Vermont Medical Center's Genomic Medicine laboratory, said in an interview. Vermont has implemented NGS in "care pathways" for oncology, pharmacogenomics, and inherited diseases and is collecting data for research it hopes will make the case nationally for the clinical utility of NGS, leading to reimbursement.

Some customers, like UVMMC, have mostly focused on using the CGW, while others, like the Moffitt Cancer Center in Tampa, Florida, have used almost every available service offered, a PierianDx spokesperson said. Both were early customers and PierianDx has since expanded to offer a variety of professional services beyond the software, including implementation services, custom assay validation, and even turnkey assays that customers can brand as their own.

But representatives from both praised the firm's willingness to engage with their unique demands as they ventured into NGS-powered clinical genomics.

"The PierianDx product made it really easy and was extremely helpful," Moffitt Chair of Anatomical Pathology Anthony Magliocco, who is not a paid advisor, said in an interview. He estimated that today, around 20 percent of the 55,000 patients seen every year receives testing handled by the CGW. "[PierianDx] came on site and worked side-by-side with our bioinformatics people and clinical scientists. When we embarked upon next-gen sequencing, we didn't really have any experience and there were not many people in the field that could help us."

"They were able to help us move forward quickly. I think we managed to get our assays running within three months," he said.

Report customization, the ability to maximize a pathologist's time, and custom assay integration were among the other features that got rave reviews from both Vermont and Moffitt.

Around the country, other healthcare systems are getting word.

**Getting Engaged**

In July 2013, Sidiropoulos, newly hired to install a clinical genomics laboratory built entirely around next-generation sequencing, took a visit to Washington University in St. Louis. UVMMC's plan was to have an Illumina MiSeq ready and waiting when she arrived in September so she could jump into validating assays.

But she knew it wasn't going to be so easy. "People underestimate this," she said . "There are all these considerations I think people don't necessarily think about because the technology is so exciting." Having started a similar program at the University of California, San Francisco she knew that she would need a so-called "dry bench" solution, something to align sequence data, call variants, annotate them, and generate reports.

So, she and her boss, Chair of Pathology and Laboratory Medicine Debra Leonard, went out to appraise Wash U's Clinical Genomicist Workstation, a software suite developed as an end-to-end solution for clinical NGS. At the time of their visit, Wash U had only recently announced the CGW several months prior, in March 2013 at the Summit on Translational Bioinformatics. During their meeting, Rakesh Nagarajan, director of biomedical informatics at Wash U's Genomics and Pathology Services, led Sidiropoulos to an entire floor housing the team responsible for building and maintaining the software, curating variants, and offering interpretations.

Sidiropoulos said she will never forget the feeling she had as she walked through that floor.

"I knew that with the resources we had, there was no way to create something that would rival a system like the CGW," she said. Later, when Nagarajan offered to let UVMMC beta-test the CGW, Sidiropoulos and Leonard didn't hesitate to take them up. "It was like a gold nugget fell out of the sky and hit me in the lap," she said. "I felt like, yes, this is exactly what I need to make my program go."

Three years later, Sidiropoulos couldn't be happier. "It's delivered on every major point that I needed it to deliver on," she said. More than that, PierianDx has been a "creative partner" that has supported her every step of the way. In return, she's given the company plenty of feedback and was formally signed on as a paid advisor last summer.

Rather than feeling like she's outsourced her data to a black box, Sidiropoulos feels intimately connected to the process. "We have calls with the support team every single week. I know how the pipelines are set up, I know what our parameters are, inside and out. If I don't, I never hesitate to reach out and say, 'What does this mean?' They're quick to educate me. I'm at a completely new place of understanding."

"We really feel like they're part of our team," she said.

**Making the most of the network**

At Moffitt, NGS is often reserved for advanced cases of metastatic tumors, or rare cases. "These mutations are so variable that each patient is almost an n of one," Magliocco said. "The more we can learn about what others have learned about certain mutations and try to match patients with similar ones, the better."

"As we go down the long tail of mutations, where they become increasingly rare, we really have to pool our resources to get enough patients to make meaningful conclusions about what a specific mutation means," he said.

He noted that making sense of mutations is one of the biggest demands on a molecular pathologists' time. "With the current reimbursement models, that valuable activity is not well compensated and usually done at a loss for the lab," he said. "The more help the lab can get to optimize the pathologist's time, the better."

The network of customers can also help out in a more tangible way, by running assays for other customers. Moffitt once used this service to outsource work on a malignant hematology panel when they didn't have the reagents in-house.

The network could also leverage unused capacity at one location to help meet demand elsewhere. "If that's convenient for us in terms of managing the specimen, the data, and

the billing and doing it in a HIPAA-compliant way, we'd be very keen to consider that," Magliocco said.

**EMR Pain Points**

While connectivity between customers on the CGW is easy, connectivity with other information systems in the modern healthcare system isn't necessarily so.

Both Vermont and Moffitt mentioned issues connecting to their EMRs (Vermont uses Epic, while Moffitt uses Cerner Millennium). But they were quick to point out that the fault doesn't lie with PierianDx.

Magliocco said Moffitt's EMR integration was suboptimal. "I don't believe it's an issue with PierianDx, it's more an issue with our EMR and the complexity of it," he said.

"Pierian was there to come to the table to discuss connectivity every time we presented them with a wishlist of something we wanted to do," Sidiropoulos said. But the EMRs and the LIMS "are not in a space where they're ready to accept that type of data."

Still, the reports are only available in the EMR as a pdf file. That's not exactly what the braintrust at the National Academy of Sciences have in mind to make the most of personalized medicine. Last year, the National Academies published a report called "Biomarker Tests for Molecularly Targeted Therapies: Key to Unlocking Precision Medicine," bemoaning the lack of structured data in most EMRs.

"Although progress has been achieved at the level of genomic data exploration, incorporation into health care records has yet to be fully realized," the report said. The authors called on EMR and LIMS vendors and other software developers to "enable the capture and linkage of biomarker tests, molecularly targeted therapies, and longitudinal clinical patient data in the EHR to facilitate data transfer into one or more national databases."

At a minimum, the report recommended that the EMR support structured data types including specimen requirements, specific results and their interpretation, treatments and tests ordered, and longitudinal clinical patient data.

**Reports and Reporting**

However, Sidiropoulos said she likes the CGW reports and took great pains to preserve the report format.

"It feels like a win to choose the best [hardware and software] solutions for your own lab, but you're not always thinking about how they connect to the rest of your world," namely the EMR, she said. Because anatomic pathology or laboratory medicine departments will have their own laboratory information systems with their own entry points into the EMR, institutions will try to leverage those connections. "But you lose the fidelity of a report format by trying to leveraging someone else's mechanism of getting into the EMR," she said.

Report generation and customization is another aspect of the PierianDx experience that both Vermont and Moffitt highlighted. Both have spent effort internally to work with their physicians to better understand how to package the data.

And the CGW-generated draft reports are a huge bonus for pathologists reviewing them before finalized versions are sent out for, say, an oncologist to use in a patient's care plan.

"As a pathologist, the system notifies me when there's a report ready to review," Magliocco said. Reports are available through a secure web server, so even while travelling he can look at files, even individual reads. "It'll display suggested reports based on the mutational profiles that are seen. I may not use an existing report — often I'll edit it with my own knowledge — but it does make it convenient to package and sign it out quickly. The efficiency is remarkable," especially when compared to surgical pathology reporting in the EMR.

The software can also grow with the individual customer. "My sign-out gets quicker over time, because it learns our interpretations," Sidiropoulos said. "We aren't having to recreate the wheel every time. As we've set up reflex testing in various cancer types, we have been well supported to scale the massive undertaking it is to do a medical sign-out and generate a clinically relevant report."

For Vermont, PierianDx also offers another major benefit, the ability to support healthcare delivery research on the clinical utility of NGS. "A lot more health services research has to go on so we can publish on the value of genomics in the clinical space, so we can move the needle on getting paid for doing it," Sidiropoulos said. To that end, Vermont has partnered with GenoSpace and PierianDx was ready and willing to help move the data into that tool.

"Now we can just search our data and look at what we're doing, see what trends pop out at us. It's like taking off a blindfold," she said.

Sidiropoulos said she's especially excited to see Dartmouth-Hitchcock come onboard. "Together, we have a unique landscape," she said. "Being on the same system is going to facilitate doing our part to move the needle nationally."